Department of Veterans Affairs **VHA DIRECTIVE 2008-014**
Veterans Health Administration
Washington, DC 20420 **March 12, 2008**

AUDITING OF VHA HUMAN SUBJECTS RESEARCH TO DETERMINE COMPLIANCE WITH APPLICABLE LAWS, REGULATIONS, AND POLICIES

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy requiring the periodic auditing of Department of Veterans Affairs (VA)-approved human subjects research to assess compliance with all applicable laws, regulations, and policies including those related to privacy, confidentiality, and information security requirements.

2. BACKGROUND: As a public agency, VHA has an obligation to preserve public trust in the integrity and quality of research carried out by its investigators, involving subjects in VA research, and in its facilities. VA must exercise prudent stewardship of public resources, including public funds that support research programs. Appropriate mechanisms must be in place to evaluate the functioning of the Human Research Protection Program (HRPP) and the safeguards in place to protect human research subjects in VA research.

a. Auditing is a mechanism to evaluate VA's human subject research program and, when appropriate, identify areas for corrective action. An active auditing program should provide reasonable assurance of the integrity of the research program and that adequate protections for research subjects are in place.

b. VHA Handbook 1200.5 currently requires that the Institutional Review Board (IRB) develop written procedures for conducting audits of protocols and other IRB activities. This Directive requires that specific policies are in place for periodic and random audits of human subject research protocols and HRPP processes, which require appropriate and timely corrective actions when deficiencies are identified.

c. **Definitions**

(1) **Institutional Review Board (IRB).** The IRB is a board established in accordance with, and for the purposes expressed in, the Common Rule (Title 38 Code of Federal Regulations (CFR) 16.102(g)). It is responsible for the review of, approval or disapproval of, and continuing oversight of research involving human subjects.

(2) **Human Subjects Research.** Human subjects research is research that involves human subjects.

(a) As defined in the Common Rule (38 CFR 16) and VHA Handbook 1200.5, a human subject is a living individual about whom an investigator conducting research obtains:

1. Data through intervention or interaction with the individual, or

2. Identifiable private information.

(b) An intervention includes both physical procedures by which data are gathered and all manipulations (physical, psychological, or environmental) of the human subject, or the subject's environment, that are performed for research purposes.

(c) Interaction includes communication or interpersonal contact between the investigator and the human subject.

(3) **Research.** As defined by the Common Rule (38 CFR 16.102(d)) research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

3. POLICY: It is VHA policy that each Director of a VHA facility conducting human subjects research ensure that the local HRPP conducts periodic audits of VA-approved research to assess compliance with all applicable laws, statutes, regulations, and policies including those related to privacy, confidentiality, and information security requirements.

4. ACTIONS

a. **Facility Director.** The facility Director is responsible for:

(1) Identifying which office or entity at the facility is responsible for:

(a) Developing the applicable policies;

(b) Conducting the audits; and

(c) Documenting the audits and reporting the results to the IRB and other entities or persons as required by VHA and local policies and procedures (e.g., the Office of Research Oversight, the Office of Research and Development, the Office of Human Research Protections, the Food and Drug Administration, sponsors).

(2) Evaluating, at least annually, the effectiveness of the auditing program.

(3) Ensuring that adequate resources and personnel are made available to achieve the objectives of this policy.

b. **Entity Responsible for the Auditing Program.** The office or entity responsible for the auditing program is responsible for:

(1) Developing the policies and the accompanying standard operating procedures (SOPs) for the auditing program. The policies and SOPs must address the:

(a) Expertise required for conducting the audits and class of individuals responsible for the auditing

(b) Frequency of the audits and the type of audits to be conducted based on such criteria as risk to human subjects, importance of the issue to HRPP operations, and local HRPP concerns

(c) Areas to be audited. These need to include, but are not limited to: inclusion and exclusion criteria, documentation of informed consent; waiver of informed consent; Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant authorization; waiver of HIPAA compliant authorization and the required documentation by the IRB or Privacy Board; security of the data; compliance with all data security requirements; and compliance with all privacy and confidentiality requirements; and

(d) Adequacy of HRPP processes, such as:

1. The effectiveness of communication with all applicable committees, persons, and officials; and

2. The documentation of compliance with VA and other requirements.

(2) Ensuring documentation and reporting requirements of the auditing program, which must include:

(a) Content of the reports;

(b) Persons, officials, or committees that must receive and review reports (e.g., the Principal Investigator, IRB, Research and Development (R&D) Committee, Assistant Chief of Staff (ACOS) for R&D, and other administrative persons as appropriate);

(c) Timeframe for reporting;

(d) Corrective actions required by the IRB, R&D Committee, or other appropriate entities to be taken based on the findings;

(e) Who should implement and review the corrective actions; and

(f) Evaluation of the results of the corrective actions by the entity(ies) requiring such actions.

5. REFERENCES

a. VHA Handbook 1200.5,

b. VHA Handbook 1605.1.

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) and the VHA Privacy Officer (19F) are responsible for the contents of this Directive. Questions may be addressed to 202-254-0183 (ORD).

7. RECISSIONS: None. This VHA Directive expires March 31, 2013.

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